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July 29, 2004

File: 4001.002299

CERTIFICATE OF MAILING
37 C.F.R. § 1.8

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Arlington, VA 22313-1450, on the date below:

July 29, 2004 — Date

Shelley P.M. Fussey

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RE: *U.S. Patent Application Serial No. 09/998,833; Entitled "Combined Cancer Treatment Methods Using Antibodies to Aminophospholipids"; Thorpe & Ran (UTSD:549--2); Peregrine Ref. No. UTS4 0104(US)USC1*

Sir:

Enclosed for filing in the above-referenced patent application is:

(1) A Response to Restriction Requirement (with Exhibit A) dated July 14, 2004; and

(2) A return postcard to acknowledge receipt of these materials. Please date stamp and mail this postcard.

No fees should be due. However, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason relating to the enclosed materials, the Director is authorized to deduct said fees from Williams, Morgan & Amerson, P.C. Deposit Account No. 50-0786/4001.002299.

Respectfully submitted,

Williams, Morgan & Amerson, P.C.
Customer No. 23720

Shelley P.M. Fussey, Ph.D.
Reg. No. 39,458
Agent for Applicants

Encls.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Philip E. Thorpe and Sophia Ran	Group Art Unit: 1642
Serial No.: 09/998,833	Examiner: Fetterolf
Filed: November 30, 2001	Atty. Dkt. No.: 4001.002299
For: Combined Cancer Treatment Methods Using Antibodies to Aminophospholipids (As Amended)	

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July 29, 2004
Date

Shelley P.M. Fussey

RESPONSE TO RESTRICTION
REQUIREMENT DATED JULY 14, 2004

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The Examiner is respectfully requested to enter and consider the present paper, which constitutes Applicants' response to the Restriction and Species Election Requirement dated July 14, 2004 ("the Requirement"). Applicants traverse the Requirement on several grounds, but enter provisional elections. The response is timely filed and no fees should be due.

I. Restriction Requirement

The Requirement takes the position that pending claims 4-10, 23-27, 41 and 49-68 are drawn to six allegedly distinct inventions. Each invention is said to be drawn to a method for treating an animal having a vascularized tumor, comprising simultaneously or sequentially administering to the animal a therapeutically effective combination of at least a first pharmaceutical composition comprising at least a first antibody, or antigen-binding fragment thereof, that binds to an aminophospholipid on the luminal surface of blood vessels of the vascularized tumor and at least a second therapeutic agent, wherein administering the second therapeutic agent allegedly gives rise to the six distinct inventions, which are set forth as:

Group I: Claims 4-10 23-27, 41, 49-50, 57-58, 61-65 and 68, said to be drawn to the foregoing combination treatment method wherein the second therapeutic agent is a chemotherapeutic agent or a compound that interferes with tubulin activity; classified in class 424, subclass 133.11; class 514, subclass 34, 691;

Group II: Claims 4-10, 23-27, 41, 51-52, 61-62, 66-67 and 68, said to be drawn to the foregoing combination treatment method wherein the second therapeutic agent is an anti-angiogenic agent; classified in class 424, subclass 133.11; class 514, subclass 12;

Group III: Claims 4-10, 23-27, 41, 53-54, 61-65 and 68, said to be drawn to the foregoing combination treatment method wherein the second therapeutic agent is an inflammatory cytokine; classified in class 424, subclass 133.1; class 514, subclass 8;

Group IV: Claims 4-10, 23-27, 41, 55 and 68, said to be drawn to the foregoing combination treatment method wherein the second therapeutic agent is a therapeutic agent "such as H_2O_2"; classified in class 424, subclass 133.1; class 514, subclass 714;

Group V: Claims 4-10, 23-27, 41, 56 and 68, said to be drawn to the foregoing combination treatment method wherein the second therapeutic agent is a therapeutic agent "such as thrombin"; classified in class 424, subclass 94.66; and

Group VI: Claims 4-10, 23-27, 41, 59-60, 61-65 and 68, said to be drawn to the foregoing combination treatment method wherein the second therapeutic agent is a calcium-flux inducing or calcium ionophore agent; classified in class 424, subclass 133.1.

The inventions of Groups I-VI are said to be materially distinct methods (Requirement at page 4), although no reasoning is given to support such a position.

II. Traversal

Applicants respectfully traverse the Requirement on various grounds. Including that the Requirement attempts to restrict claims that are in the same class and subclass; ignores proper generic and linking claims; omits reasoning, or offers inadequate reasoning, to support restriction; and fails to establish a burden on the examiner should the claims not be restricted. Importantly, the Requirement is also in contradiction with earlier decisions of the Office that the present claims are all drawn to the same patentable invention.

The Requirement is therefore at odds with established restriction practice and Applicants respectfully traverse. Nonetheless, a provisional election is included herewith.

III. Provisional Election

Applicants provisionally elect the Group I invention with traverse.

IV. Office Decision of No Patentable Distinction

As detailed when the present application was filed, the claims issued from the parent application include claims directed to the simultaneous or sequential administration of anti-aminophospholipid antibodies, or antigen-binding fragments thereof, with at least a second anti-cancer agent. In particular, note independent claim 47 and dependent claim 48 (**Exhibit A**).

Therefore, the Office has already determined that the administration of an anti-aminophospholipid antibody, or antigen-binding fragment thereof, in combination with any second anti-cancer agent constitutes a unified invention that is not restrictable.

V. All Claims are Patentable

Equally importantly, and as detailed when this application was filed, by issuing the parent application (now U.S. Patent No. 6,406,693), the Office has already determined that the generic invention is patentable. The claims in the present continuation application are thus directed to species of combined treatment methods that were disclosed, but not claimed in the parent patent. Given that all requirements of patentability were satisfied during examination of the parent application, and the present claims are directed to species within the generic invention patented from the parent application, all pending claims in this application are in condition for allowance.

VI. Species Election Requirement and Response

The Requirement also sets forth species election requirements pertaining to Group I and Group II. With the caveat that all pending claims represent species within a generic invention, Applicants hereby elect the species of vincristine without traverse.

VII. Status of the Claims

Prior to the Requirement, claims 4-10, 23-27, 41 and 49-68 were pending. Presently, no claims have been canceled, amended or added. Claims 4-10, 23-27, 41 and 49-68 therefore remain pending in the case. In light of the language of the claims, particularly the terms "comprising" and "at least a second therapeutic agent", there are no claims that do not read on the elected species.

According to 37 C.F.R. § 1.121, as no claims have been canceled, amended or added, a listing of the pending claims is not required.

VIII. Conclusions

This is a complete response to the referenced Requirement. In conclusion, Applicants submit that the present claims are drawn to an invention that is not properly subject to restriction and that is in condition for allowance. Should Examiner Fetterolf have any questions or comments, a telephone call to the undersigned Applicant's representative is earnestly solicited.

Respectfully submitted,
Williams, Morgan & Amerson, P.C.
Customer No. 23720

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